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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,131	02/13/2004	Brigitte Gicquel	02356.0090	3675

22852 7590 11/15/2005

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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/777,131	GICQUEL, BRIGITTE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-43 and 45 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/04, 5/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's Response to Restriction Requirement, received 24 August 2005, is acknowledged. Applicant elects, without traverse, invention II, claims 26-43 and 45, drawn to DNA and vectors, classified in class 536, subclass 23.7.

Claims 1-45 are pending. Claims 1-25 and 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 26-43 and 45 are under consideration.

### **Priority Statement**

3. The priority statement at the beginning of the specification should be amended to recite that the instant application is a continuation of the listed pct.

### **Specification**

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 20, bottom of page; page 21, first line). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The disclosure is objected to because of the following informalities:

Page 1, paragraph 004, line 3, "id ntical" should be "identical"; line 4, "Thes " should be "these", "gen type" should be "genotype",

Page 6, first line, "th " should be "the"; paragraph 021, line 2, "polypeptid " should be "polypeptide",

Page 8, last line, "th method" should be "the method",

Page 10, paragraph 032, line 3, "sequence" should be "sequences",

Page 12, line 1, "th open" should be "the open",

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Page 19, line 2, should there be an "e" at the end of deoxyguanosin and adenin?,

Page 23, line 1, "of ther" should be "of other"; line 3, what is the meaning of "2,"

Page 24, line 2, "B ijing" should be "Beijing",

Page 28, line 2, "th Beijing" should be "the Beijing" paragraph 079, line 3, is this "new ref. 28" different from the reference numbered 28 on page 42,

Page 34, paragraph 099, refers to "Matthews et al. 1988", but no such reference is in the list on pages 40-43,

Page 35, line 1, "appropriat " should be "appropriate"; paragraph 0101, refers to "as described in Sambrook et al, in 1989", and "described in 1986", but no such references are in the list on pages 40-43,

Appropriate correction is required.

### **Claim Objections**

6. Claim 42 is objected to because of the following informality: line 2, "polynucleotid " should be "polynucleotide". Appropriate correction is required.

### **Claim Rejections - 35 USC § 101**

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 26-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to polynucleotides which contain various sequences, or consists of contiguous nucleotides of the *mutT2* locus of a *M. tuberculosis*. There is no recitation of

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isolation or purification and according to applicant's own specification, the described polynucleotides have been observed in nature.

**Claim Rejections - 35 USC § 112**

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 26-27 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims 26 and 27 are drawn to a polynucleotide consisting of contiguous nucleotides of the Rv908 locus of a *M. tuberculosis* strain including codon 48 wherein codon 48 is GGG, or a polynucleotide fully complementary thereto.

The actual codon at position 48 is entirely dependent upon what is considered as the exact sequence of Rv908. However, the claims do not recite a particular sequence identification number for the Rv908 locus. Thus, it is unclear what is the actual sequence(s) being claimed.

The claims 29 and 30 are drawn to a polynucleotide consisting of contiguous nucleotides of the *mutT2* locus of a *M. tuberculosis* strain including codon 58 wherein codon 48 is CGA, or a polynucleotide fully complementary thereto.

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11. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites codon 58. Claim 30 depends from claim 29, but refers to codon 48. it is unclear if this is correct. If it is, then how can claim 30 be possible if claim 29 contiguous nucleotides consists of codons 50-60?

12. Claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from nonelected claims.

### **Double Patenting**

13. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

14. Claims 26-43 and 45 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 26-43 and 45 of copending Application No. 10/216,817. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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**Claim Rejections - 35 USC § 102**

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 32 and 45 rejected under 35 U.S.C. 102(e) as being anticipated by Fleischmann et al (U.S. Pat. No. 6,294,328).

The claims are drawn to a purified polynucleotide comprising SEQ ID NO:1 or 2 or 3 or 4 or 5. Fleischmann teach a purified polynucleotide (SEQ ID NO:2) which comprises the instant SEQ ID NO:1, 2, 3, 4 and 5 (residues 1285866 to 1285886; residues 1286681 to 1286665; residues 4385490 to 4385509; residues 4386625 to 4386607; residues 1478734 to 1478718)(see sequence listings).

**Conclusion**

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

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November 14, 2005